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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/592,910	05/14/2007	James H. Silver	CRD5075USPCT	6008
27777 PHILIP S. JOH	7590 11/03/201 <b>NSON</b>	EXAMINER		
JOHNSON & J	OHNSON	HOLLM, JONATHAN A		
ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ART UNIT	PAPER NUMBER
			3734	
			NOTIFICATION DATE	DELIVERY MODE
			11/03/2010	ELECTRONIC

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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	Application No.	Applicant(s)			
Office Action Comments	10/592,910	SILVER, JAMES H.			
Office Action Summary	Examiner	Art Unit			
	JONATHAN A. HOLLM	3734			
The MAILING DATE of this communication Period for Reply	appears on the cover sheet with th	ne correspondence address			
A SHORTENED STATUTORY PERIOD FOR RE WHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CFF after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory per  - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the meanned patent term adjustment. See 37 CFR 1.704(b).	E DATE OF THIS COMMUNICAT R 1.136(a). In no event, however, may a reply b riod will apply and will expire SIX (6) MONTHS to atute, cause the application to become ABANDO	ION.  e timely filed  from the mailing date of this communication.  DNED (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 23	5 August 2010				
	his action is non-final.				
· <u> </u>	, <del></del>				
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims					
<ul> <li>4) ☐ Claim(s) 1-6 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5) ☐ Claim(s) is/are allowed.</li> <li>6) ☐ Claim(s) 1-6 is/are rejected.</li> <li>7) ☐ Claim(s) is/are objected to.</li> <li>8) ☐ Claim(s) are subject to restriction and/or election requirement.</li> </ul>					
Application Papers					
9) ☐ The specification is objected to by the Exam 10) ☑ The drawing(s) filed on 15 September 2006 Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct of the correct	is/are: a)⊠ accepted or b)□ ob the drawing(s) be held in abeyance. rection is required if the drawing(s) is	See 37 CFR 1.85(a). objected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date					

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#### **DETAILED ACTION**

1. The Amendment filed 25 August 2010 has been entered. **Claims 1-6** are pending in the application. The previous objections to the drawings are withdrawn in light of Applicant's amendments to the specification. Response to applicant's arguments can be found at the end of this office action.

### Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 3. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding **claim 1**, the initial disclosure of the application does not show or describe the medical filter also comprising means for capture and removal via a catheter after the medical filter becomes endothelialized. Paragraph 0044 of the specification of the instant application states that it is preferred to leave the filter in a blood vessel once the filter has been endothelialized. Paragraph 0044 also states that the structure of the struts of the filter may tend to extend the period of time for incorporation or endothelialization to allow for more time for retrieval of the filter, but does *not* disclose

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the filter being retrieved after endothelialization. **Claims 2-6** are rejected as being dependent upon rejected claim 1.

### Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forber (US Patent Application Publication Number 2003/0023265) in view of Boyle et al (US Patent Application Publication Number 2003/0120303) and Russell (US Patent Application Publication Number 2003/0130680).

Forber discloses a medical filter for therapeutic treatment of a patient substantially as claimed, including more than on pair of ribs extending between first and second ends wherein in an expanded, deployed shape, the ribs follow an undulating path such that a first portion (L3) of each pair of ribs extends substantially adjacent to each other for a distance from the first end, and a second portion of each pair of ribs extends substantially adjacent to each other for a distance from the second end (in that the ribs converge to become adjacent at the second end), and an intermediate portion (L1) of each one of a pair of ribs tends to curve away from each other (see at least figure 2), except for the medical filter being formed from a single thin walled tube. Boyle et al teach providing a single thin walled tubular member, such as a nickel-titanium

hypotube, defining a longitudinal axis and having a first and second end, laser cutting more than one pair of struts in the tubular form so as to create a desired pattern defining the struts extending between the first and second end of the filter, and treating the struts so that they tend to resiliently expand to from a compressed shape to an expanded shape (paragraphs 0051-56). It would have been obvious to a person having ordinary skill in the art at the time of the invention to form the device of Forber by laser cutting a single thin walled tubular member to create the desired strut pattern, since Boyle et al teach such a method as being a well known technique in the art for forming a desired strut pattern in self-expandable filters.

The modified device of Forber in view of Boyle et al is not explicitly disclosed with filter being configured for long term implantation via complete separation from a delivery catheter such that the catheter may be removed and the filter including means for capture and removal via a catheter after a predetermined period of time. Russell teaches configuring a filter (10) having first and second ends with ribs extending therebetween to be completely separated from a delivery catheter (70) and providing the filter with means for capture and removal after a predetermined period of time (see figures 8A-9D). It would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device Forber in view of Boyle et al to be configured for complete separation from a delivery catheter and provided with means for capture and removal, in view of Russell, since Russell teaches that such a configuration minimizes possible migration of the filter during a procedure, which could result in damage to a blood vessel, and facilitates the completion of a clinical procedure using a

filter (paragraph 0026). As the modified device of Forber in view of Boyle et al and Russell is configured for complete separation from a delivery catheter, the modified filter is capable of long-term implantation and removal after the filter becomes endothelialized.

The modified device of Forber in view of Boyle et al and Russell is not explicitly disclosed with the filter being sized for use in the vena cava. However, Boyle et al teach configuring a filter for use in veins (paragraph 0020) and Russell teach that sizing and using filters in the vena cava is well known in the art to protect a patient from pulmonary embolism after a procedure (paragraphs 0004-0005). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Forber in view of Boyle et al and Russell to have the filter sized for use in the vena cava, in order to protect the patient from pulmonary embolism after a procedure.

Regarding **claim 2**, Forber discloses the intermediate portion (L1) of each one of a pair of ribs tends to curve away from each other and touch one of another pair of ribs (see at least figures 1, 2, and 12).

Regarding **claim 3**, Forber discloses in the expanded shape, a central portion of each rib tends to extend parallel to the longitudinal axis of the filter (see at least figures 1, 2, and 12).

Regarding **claim 4**, Forber discloses the filter has at least three pairs of ribs (see at least figures 1, 2, and 12).

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Regarding **claim 5**, the modified device of Forber, Boyle et al, and Russell, is not explicitly disclosed with six pairs of ribs. It would have been an obvious matter of design choice to include additional pairs of ribs, since applicant has not disclosed that the number of rib pairs solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with three pairs of ribs.

Regarding **claim 6**, Boyle et al discloses the filter being made of Nitinol (paragraph 56).

## Response to Arguments

- 6. Applicant's arguments filed 25 August 2010 have been fully considered but they are not persuasive.
- 7. Regarding Applicant's argument that the prior art does not disclose or suggest a medical filter for implantation until it can become endothelialized and still be removed, the limitation "means for capture and removal via a catheter after the medical filter becomes endothelialized" is being treated as an functional, intended-use limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Further, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

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As the means for capture and removal in the modified device of Forber in view of Boyle et al and Russell is capable of allowing capture and removal of the filter via a catheter after filter endothelialization, the limitations of the claims are met.

#### Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN A. HOLLM whose telephone number is (571) 270-7529. The examiner can normally be reached on Monday - Friday 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAH/

/TODD E. MANAHAN/ Supervisory Patent Examiner, Art Unit 3776